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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,261	03/09/2004	Robert G. Petit II	781.014US2	2385

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EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,261	PETIT ET AL.	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-26 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 04/30/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-26 are pending in application

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidl (US 5,438,042).

In claim 1, applicant claims a solid composition comprising a dry mixture of at least one carbohydrate and an amino acid or amino acid salt, wherein the ratio of the total carbohydrate to amino acid is about 1.5:1 w/w to about 20:1 w/w. Schmidl et al. disclose applicant's solid composition wherein 65 to 85% is carbohydrates and 14 to 30% by weight is glutamine (see abstract). This means that the total carbohydrate to amino acid is about 6:1 when the percent of carbohydrate to glutamine (amino acid) is 85% to 14%) (see abstract). Claim 2 which is drawn to the composition of claim 1, wherein the amino acid has a solubility of less than about 5 grams per 100 milliliters of water at 22-25 °C, is also anticipated by Schmidl et al., since Schmidl et al's composition which contains the same ingredients in the same proportion by weight (total

carbohydrate to amino acid) should inherently have the same solubility at said temperature range. Dependent claims 3-5, which are drawn to specific amino acids and carbohydrates are also anticipated by Schmidl et al., since Schmidl et al., composition also contains glutamine (L-glutamine) and the carbohydrate (maltodextrin) (see abstract, and example 1, col. 9, line 12 to col. 10, line 55, see also claim 1). Claim 8, which is drawn a composition of claim, containing specific % w/w glutamine and carbohydrate, are also anticipated by Schmidl et al. since in Schmidl et al.'s composition the total carbohydrate to amino acid is about 6:1 when the percent of carbohydrate to glutamine (amino acid) is 85% to 14%) (see abstract). In claim 9, applicant claims a solid composition comprising a dry mixture of at least one carbohydrate and glutamine, wherein the concentration of glutamine is about 5-15% w/w and the concentration of carbohydrate is about 30-50% w/w. Schmidl et al. disclose applicant's solid composition wherein 65 to 85% is carbohydrates and 14 to 30% by weight is glutamine (see abstract). This means that the total carbohydrate to amino acid is about 6:1 when the percent of carbohydrate to glutamine (amino acid) is 85% to 14%) (see abstract). Claims 10 and 11, which are drawn to a composition of claim 9, containing specific amino acids and carbohydrates are also anticipated by Schmidl et al., since Schmidl et al., composition also contains glutamine (L-glutamine) and the carbohydrate (maltodextrin) (see abstract, and example 1, col. 9, line 12 to col. 10, line 55, see also claim 1).

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skubitz et al. (US 5,438,075).

In claim 1 applicant claims "A solid composition comprising a dry mixture of at least one carbohydrate and an amino acid or amino acid salt, wherein the ratio of the total carbohydrate to

amino acid is about 1.5:1 w/w to about 20:1 w/w. Dependent claims 3-8 are drawn to said composition containing the amino acid glutamine (L-glutamine), specific carbohydrates including sucrose and sorbitol, and specific % w/w concentrations of glutamine to total carbohydrate.

Skubitz et al. disclose a composition for treating mucositis comprising L-glutamine, sucrose, glycerin, sorbitol, citric acid, Na_3PO4, cellulose and carboxymethylcellulose, carrageenan, and xanthum gum (see col.5, lines 3-16).

The difference between applicant's claimed composition and the composition of Skubitz et al. is that Skubitz et al. composition is in an aqueous suspension form, and Skubitz et al. do not disclose the exact ratio by weight percent carbohydrate to L-glutamine. However, Skubitz et al. disclose that other carriers (i.e other than water), flavoring enhancers, gums and suspending agents can be used (col. 5, lines 3-16), and the weight percent carbohydrate to L-glutamine used dependents on factors like the severity of the disease or condition and age or weight of the patient treated (col. 5, lines 3-16). In fact, it should be noted that Skubitz et al.'s composition must have been prepared in solid form before the water was added to produce the suspension. Furthermore, Skubitz et al. disclose that their composition can be formulated or supplied orally or topically in forms that includes as a paste, gel, foam or ointment form (col.7, lines 55 to 68).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared Skubitz et al.'s composition to treat mucositis and to use any form of the composition that contains different ratios of the same ingredients disclosed by Skubitz et al., depending on need such as the severity of the disease or condition and the age or weight of the patient treated.

One having ordinary skill in the art would have been motivated, to have prepared Skubitz et al.'s composition to treat mucositis and to use any form of the composition that contains different ratios of the same ingredients disclosed by Skubitz et al., depending on need such as the severity of the disease or condition and the age or weight of the patient treated.

In claim 9, applicant claims a solid composition comprising a dry mixture of at least one carbohydrate and glutamine, wherein the concentration of glutamine is about 5-15% w/w and the concentration of carbohydrate is about 30-50% w/w. Dependent claims 10-12 are drawn to said composition, containing specific amino acids and carbohydrates. Claim 13 is drawn to a composition of claim 9 further comprising glycerin. Claim 14 is drawn the composition of claim 13 further comprising xanthum gum, carrageenan or a combination thereof. Claim 15 is drawn to a composition of claim 14 further comprising sodium phosphate, artifical flavors .....

Skubitz et al. disclose a composition for treating mucositis comprising L-glutamine, sucrose, glycerin, sorbitol, citric acid, Na_3PO4, cellulose and carboxymethylcellulose, carrageenan, and xanthum gum (see col.5, lines 3-16).

The difference between applicant's claimed composition and the composition of Skubitz et al. is that Skubitz et al. composition is in an aqueous suspension form, and Skubitz et al. do not disclose the exact ratio by weight percent carbohydrate to L-glutamine. However, Skubitz et al. disclose that other carriers (i.e other than water), flavoring enhancers, gums and suspending agents can be used (col. 5, lines 3-16), and the weight percent carbohydrate to L-glutamine used dependents on factors like the severity of the disease or condition and age or weight of the patient treated (col. 5, lines 3-16). In fact, it should be noted that Skubitz et al. composition must have been prepared in solid form before the water was added to produce the suspension.

Furthermore, Skubitz et al. disclose that their composition can be formulated or supplied orally or topically in forms that includes as a paste, gel, foam or ointment form (col.7, lines 55 to 68).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared Skubitz et al.'s composition to treat mucositis and to use any form of the composition that contains different ratios of the same ingredients disclosed by Skubitz et al., depending on need such as the severity of the disease or condition and the age or weight of the patient treated.

One having ordinary skill in the art would have been motivated, to have prepared Skubitz et al.'s composition to treat mucositis and to use any form of the composition that contains different ratios of the same ingredients disclosed by Skubitz et al., depending on need such as the severity of the disease or condition and the age or weight of the patient treated.

In claim 16, applicant claims "A solid composition consisting essentially of a dry mixture of about 5- 15% w/w glutamine; about 30-50 w/w% carbohydrate, an effective amount of buffer or buffering agent; and about 1-5% w/w modified cellulose." Claims 17-26 which are further limitation, are drawn compositions containing specific amino acids glutamine (L-glutamine), specific carbohydtates, specific buffering agent (anhydrous monobasic sodium phosphate), glycerin, specific peservatives, stabilizers, flavoring, emulsifying agents and defoamant.

The difference between applicant's claimed composition and the composition of Skubitz et al. is that Skubitz et al. composition is in an aqueous suspension form, and Skubitz et al. do not disclose the exact ratio by weight percent carbohydrate to L-glutamine. However, Skubitz et al. disclose that other carriers (i.e other than water), flavoring enhancers, gums and suspending agents can be used (col. 5, lines 3-16), and the weight percent carbohydrate to L-glutamine used

dependents on factors like the severity of the disease or condition and age or weight of the patient treated (col. 5, lines 3-16). In fact, it should be noted that Skubitz et al. composition must have been prepared in solid form before the water was added to produce the suspension. Furthermore, Skubitz et al. disclose that their composition can be formulated or supplied orally or topically in forms that includes as a paste, gel, foam or ointment form (col.7, lines 55 to 68).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared Skubitz et al.'s composition to treat mucositis and to use any form of the composition that contains different ratios of the same ingredients disclosed by Skubitz et al., depending on need such as the severity of the disease or condition and the age or weight of the patient treated.

One having ordinary skill in the art would have been motivated, to have prepared Skubitz et al.'s composition to treat mucositis and to use any form of the composition that contains different ratios of the same ingredients disclosed by Skubitz et al., depending on need such as the severity of the disease or condition and the age or weight of the patient treated.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

January 7, 2004.

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600